

Remarks

Claims

Claims 1, 3-15, 17, 19, 24-27, 30, 31, 35-37, 39-40, and 51-58 are pending and under examination. Claims 2, 16, 18, 28, 34, 38, and 49 previously were cancelled. Claims 20-23, 29, 32, 33, 41-48, and 50 are withdrawn. Claims 7, 17, 27, 41, 44-48 are hereby cancelled without prejudice. The following claims under examination are amended herein: 1, 3-6, 8-9, 11-12, 19, 24-25, 30-31, 35-36, 39-40, 52-58. The following withdrawn claims are amended herein: 20-23, 29, 32, 42-43. Rejoinder of withdrawn claims under M.P.E.P. § 821.04 is hereby requested.

Claim 1 is amended herein to recite two classes of compounds: (1) acid addition salts of a 5-ALA ester wherein the acid is nitric acid, the 5-ALA ester is a compound of formula (X), and the ester substituent R¹ is “a straight-chained C₁₋₆ alkyl group substituted by an aryl group,” and (2) acid addition salts of a 5-ALA ester wherein the acid is “a sulfonic acid or a sulfonic acid derivative,” the 5-ALA ester is a compound of formula (XI), and the ester substituent R⁴ is “a straight-chained C₁₋₆ alkyl group optionally substituted by an aryl group.” The dependent claims have been amended to reflect and incorporate these changes. Thus, for example, claim 5 depends from claim 1 and is amended in part to recite that “said acid is nitric acid” and by deleting “5-ALA methyl ester, 5-ALA hexyl ester.” Similarly, claim 36, which depends from claim 3 (limited to nitric acid salts), is amended to no longer recite C₁₋₆ alkyl esters.

Claims 29 and 32 are amended to refer to “photoactivating light.” Support for these amendments can be found at least, for example, in paragraphs [0002], [0007], [0011], and [0107] of the specification as published. Some of the claims have also been amended to respond to rejections under 35 U.S.C. § 112 or to respond to objections to the claims, as detailed below.

These amendments add no new matter. All amendments are made to expedite prosecution and without prejudice and Applicants reserve the right to pursue any unclaimed subject matter in a continuing or divisional application.

Response to Rejections

The Examiner has withdrawn the previous indefiniteness rejection under 35 U.S.C. § 112, the double patenting rejection except with respect to claims 24 and 25, and the prior obviousness rejections in view of the Applicants' previous amendment and remarks. The remaining rejections and the new 35 U.S.C. § 112 and 35 U.S.C. § 102(b) rejections and claim objections are addressed below.

In sum, the pending claims recite certain acid addition salts of 5-aminolevulinic acid and compositions, products, and kits comprising such acid addition salts. The Examiner has issued a new rejection alleging that some of the claim-recited acid addition salts are generally disclosed in the cited Japanese patent application by Takeya. Certain claims to acid addition salts were not rejected over Takeya, indicating that the Examiner concedes that the acid addition salts recited by those claims are not disclosed by the cited application. To expedite prosecution, the present claims reciting compounds have been amended to recite only the acid addition salts that the Examiner implicitly has conceded are not disclosed by Takeya.

Rejections Under 35 U.S.C. § 112

Claims 4-6 are rejected as indefinite for depending from cancelled claim 2. Claims 4-6 have been amended to depend from claim 1.

Claims 9-11 are rejected as indefinite for not defining the ester substituent R¹. Claims 9-11 as amended no longer recite a compound of formula I having a substituent R¹. Further, claims 9-11 ultimately depend from claim 1, which clearly defines R¹ through R⁶. In view of these amendments, Applicants believe the indefiniteness rejections of claims 4-6 and 9-11 should be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1, 3, 5-7, 17, 19, 24-27, 35, and 36 are rejected as anticipated by Takeya (Unexamined Japanese patent application H4-9360). The rejected claims are directed to acid addition salts except for claim 26, which is directed to a pharmaceutical composition. Applicants traverse the rejection in view of the present amendment. Though not explicitly stated, the

rejection appears to be based on an alleged general disclosure by Takeya of nitric acid salts of alkyl esters of 5-aminolevulinic acid ("5-ALA"). Applicants note that the Examiner did not reject as anticipated claim 4, which depends from claim 1 but is limited to the aryl ester substituents benzyl and substituted benzyl. Further, the rejection does not appear to be based on any alleged disclosure of any acid salts of 5-ALA wherein the acid is a sulfonic acid or a sulfonic acid derivative. For example, claim 8, which required that the acid "is a sulfonic acid or a sulfonic acid derivative," was objected to, not rejected, and was said to be allowable if rewritten in independent form. Office Action at 7. Applicants therefore understand that the Examiner does not consider Takeya to disclose the nitric acid salts of arylalkyl esters of 5-ALA or the sulfonic acid or sulfonic acid derivative salts of 5-ALA esters currently recited by claim 1 as amended. Claims 3, 5-7, 17, 19, 24-27, 35, and 36 depend from or otherwise incorporate the amendments of claim 1. In view of the current amendments to claim 1, Applicants respectfully request that the anticipation rejection of claims 1, 3, 5-6, 19, 24-26, 35, and 36 be withdrawn. Claims 7, 17, and 27 are hereby cancelled, rendering moot the rejections of these claims for anticipation.

Obviousness-type Double Patenting Rejections

Claims 24 and 25 are rejected for obviousness-type double patenting in view of U.S. Patent No. 7,287,646, claims 1, 10, and 19, and in view of U.S. Patent No. 7,217,736, claims 1 and 7. The Examiner concedes that the ALA esters recited in claim 1 as amended by the previous amendment are outside the scope of the '736 and '646 patents. Office Action at 8. Further, the Examiner suggests that claims 24 and 25 would not have been rejected in view of the '736 and '646 patents if claims 24 and 25 had been subject to the same amendment. *See id.* Claim 1 as amended herein recites a narrower class of ALA esters than claim 1 of the previous amendment and thus the esters now recited by claim 1 necessarily are also outside the scope of the '736 and '646 patents. Claims 24 and 25 as presently amended recite a class of esters of the same scope as claim 1. In view of the amendments of claims 1, 24, and 25, Applicants believe that the obviousness-type double patenting rejections should be withdrawn.

Response to Claim Objections

Claim 8 is objected to as being dependent upon a rejected base claim. Applicants believe that the amendments herein to the base claim 1 should overcome the pending rejection.

Applicants respectfully request therefore that the objection to claim 8 be withdrawn. Similarly, Applicants respectfully request that the objections to claims 12-15, 37, 39, 40, and 51-58 be withdrawn because the amendments herein to any rejected claims from which claims 12-15, 37, 39, 40, and 51-58 depend should overcome the pending rejections.

The objections to claims 30 and 31 should be withdrawn because the claims have been rewritten in independent form.

Conclusion

In view of the foregoing amendments and remarks, it is believed that the subject claims are in condition for allowance, which action is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney. The Office is authorized to charge any fees that may be necessary for consideration of this paper to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

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